

Volcano Corporation – Traditional 510(k) – Modified Sync-Rx™ System  
510(k) Summary

## 510(k) Summary

### Introduction

This document contains the 510(k) Summary for the modified Sync-Rx™ System. The content of this summary is based on the requirements set forth in 21 CFR 807.92(c).

**Applicant:** Volcano Corporation

**Establishment Registration Number:** 2939520

### Contact Information:

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**Date Prepared:** August 9, 2013

**Device Trade Name:** Sync-Rx™ System

**Classification Name:** Image-intensified Fluoroscopic X-ray System

### Device Classification:

Classification: II  
Classification Panel: Radiology  
Regulation Number: 21 CFR 892.1650  
Product Code: OWB

### Predicate Devices:

The modified Sync-Rx System is claimed to be substantially equivalent to the following legally marketed predicate devices:

The Sync-Rx System (K100849) manufactured by Sync-Rx, Ltd.

The Artis Q (K123529) manufactured by Siemens Medical Systems, Inc.

### Performance Standards:

This 510(k) submission was written in accordance with the FDA Guidance document "Guidance for the Submission of Premarket Notifications for Medical Image Management Devices- July 27, 2000", "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11 2005", and "General Principles for Software Validation; January 2002". The design of the Sync-Rx System conforms to the following voluntary standards:

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IEC/EN/UL 60601-1:2005 (3rd Ed.) *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

IEC/EN 60601-1-2:2007 *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-6:2010 *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*

IEC 62366:2007 *Medical devices – Application of usability engineering to medical devices*

IEC 62304:2006 *Medical device software – Software life cycle processes*

ISO 15223:2012 *Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements*

**Device Description:**

The modified Sync-Rx System is an image acquisition and processing workstation situated in the coronary catheterization lab and intended to be used during coronary catheterizations.

The modified Sync-Rx System captures the angiographic and intravascular ultrasound (IVUS) image streams and performs the following display functions for assisting the interventional cardiologist:

During lesion evaluation: Angiogram and IVUS image selection, quantitative coronary measurements (lesion diameters, length, % stenosis) and vessel region enhancement and vessel region stabilization are performed instantly and on-line.

During device positioning, deployment and post-deployment: An on-line image stream derived from the native angiographic image stream that is enhanced and stabilized, is displayed side-by-side to the native angiographic and IVUS image streams.

Display of native image / data streams used before or during trans-catheter cardiovascular interventions, leading to a joint display of images corresponding to the same selected vascular locations or segments (also known as co-registration).

All functions performed by the modified Sync-Rx System are presented, both in the procedure room and in the control room, on a computer display that is situated directly next to the existing display of native angiographic and IVUS image streams. The modified Sync-Rx System operates by means of multiple software modules and associated algorithms interacting with one another and responsible for the on-line acquisition, processing and display of coronary image frames.

The most significant change to the modified Sync-Rx System, and the reason for this 510(k) submission, is the addition of the capability to display and co-register another native image stream, IVUS. The addition of the co-registered IVUS image stream is intended to automate manual registration processes currently performed in the coronary catheterization lab and to provide a simple means to view both the angiographic and IVUS image streams on adjacent windows on a single computer display.

**Indication for Use:**

The Sync-Rx System is an image acquisition and processing system. It is indicated for use as follows:

- To provide quantitative information regarding the calculated dimensions of arterial segments.
- To enhance visualization of the stent deployment region.
- To be used in-procedure in the catheterization lab and off-line for post-procedural analysis.
- To obtain a co-registration of an angiographic x-ray image and IVUS images.

**Comparison of Technological Characteristics:**

The modified Sync-Rx System and its identified predicate devices have the same or similar technological characteristics. The most significant technological change in the modified Sync-Rx System is the addition

of the IVUS image source and the corresponding co-registration of the angiogram and IVUS images. The additional ultrasound display and co-registration function are similar to the existing co-registration of the ECG signal with the angiogram images in the unmodified Sync-Rx System. The co-registration function is intended to simplify and automate what is done manually today in the catheterization lab when both X-Ray and IVUS images are available on individual displays. Furthermore, the addition of the IVUS image source to the System and co-registration of image streams to simplify work flow is a function currently included in the Artis Q System which also co-registers angiogram and IVUS images.

#### Application

Both the unmodified and the modified Sync-Rx Systems function as accessories to existing vessel imaging systems by providing QCA and image enhancement functions; the modified Sync-Rx System simply expands imaging sources to include IVUS images. No other functions of the System have been significantly modified. This addition of a second image source does not change how either angiography or IVUS imaging machines are used in the clinical setting, nor does it affect the QCA capability on the angiogram images as it was discussed in K100849. The modified Sync-Rx System will co-register the IVUS images with the X-Ray images in a substantially equivalent manner to the Artis Q.

The most notable technical difference between the modified Sync-Rx System and the Artis Q is that the Artis Q is primarily an imaging device that includes accessory software for image manipulation, including IVUS co-registration and QCA. Both the software component of the Artis Q and the modified Sync-Rx System are capable of acquiring angiogram and IVUS images for co-registration, QCA, and image enhancement options.

#### Image Source

The images used by the modified Sync-Rx System and its identified predicate devices are digital and analog video signals, and all aforementioned devices use native vascular images for all device functions. Both the modified Sync-Rx System and the Artis Q capture IVUS and X-Ray images of a patient's vasculature to improve visualization and to provide quantitative vessel measurements during guided procedures.

#### IVUS Measurements

The modified Sync-Rx System's application of QCA functionality to the added IVUS image stream to perform intra-luminal measurements (diameter and length) is substantially equivalent to that of the Artis Q, which was demonstrated to be safe and effective in K123529. The intra-luminal measurements performed by the modified Sync-Rx System are a subset of the intra-luminal measurements performed by the Artis Q. Performance data demonstrates that any differences in the available intra-luminal measurements between the modified Sync-Rx System and the Artis Q do not raise questions of substantial equivalence.

Although IVUS QCA measurements are not available in the unmodified Sync-Rx System, because the unmodified System does not capture IVUS as an image stream, the same statistical methods that were employed in the unmodified System to establish the accuracy and precision of the angiogram QCA measurements were employed in the modified System to establish the accuracy and precision of the IVUS QCA measurements (length and diameter). Therefore, the accuracy and precision of the IVUS measurements do not raise questions of substantial equivalence.

#### **Comparison of Indications for Use / Intended Use**

The intended use of the modified Sync-Rx System remains unchanged from that of the unmodified Sync-Rx System. The modified Sync-Rx System and its identified predicate devices are all intended for capturing native vascular images of patients with cardiovascular diseases for image processing and enhancement. Further, the modified Sync-Rx System and its predicate devices are capable of off-line use for immediate post-procedural analysis.

The Indications for Use for the modified Sync-Rx System is expanded to include the Co-Registration functionality compared to the cleared unmodified Sync-Rx System. Although the indications for use of the Artis Q focus on its intended use as an angiography system, the intended use and functionality of the image processing software component of the Artis Q are nearly identical to that of the modified Sync-Rx

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**System.** Both the modified Sync-Rx System and the Artis Q image processing software component are accessories to vascular imaging systems intended to acquire and co-register native X-Ray and IVUS images for image manipulation and processing to provide calculated vessel measurements. The unmodified Sync-Rx System functions in a similar manner, with the only exception of being a software accessory exclusively for angiography systems. The minor differences in the application between the modified Sync-Rx System and the predicate devices do not impart new intended uses or change the therapeutic effects of the device.

**Target User and Patient Population**

The intended target user group for the modified Sync-Rx System and its predicate devices is experienced and qualified medical personnel, such as clinicians, technicians and research personnel.

The modified Sync-Rx System is also intended for use for the same patient population as all of the identified predicate devices, which are patients with cardiovascular diseases whom would benefit from such treatment.

**Use Environment**

The environment of use of the modified Sync-Rx System and its predicate devices are identical. The modified Sync-Rx System and its predicate devices are all intended to be used in the catheterization lab on-line during the procedure, as well as off-line for immediate post-procedural analysis.

**Performance Test Data:**

The modified Sync-Rx System has been subjected to safety, performance, verification and validation testing before its release. Final testing of the modified Sync-Rx System included various performance tests and software validation tests, designed to ensure that the device met all of its functional requirements and intended uses. Tests have been performed to ensure that the device complies with all applicable industry and safety standards. The following list summarizes the testing performed on the modified System:

- Software Unit Tests
- Software Verification Tests
- Software Validation Tests
- Co-registration Validation – Phantom Based Simulated Environment
- Sync-Rx System Usability Validation
- Sync-Rx System Design Verification
- Electrical Safety
- Electromagnetic Compatibility

Animal test data and clinical data were not required to demonstrate substantial equivalence of the modified Sync-Rx System in this 510(k) submission.

**Substantial Equivalence:**

The modified Sync-Rx System is substantially equivalent with respect to the intended use, technological characteristics, performance characteristics, target user and patient population, and use environment to the following the legally marketed predicate devices:

- Sync-Rx System, Sync-Rx Ltd., K100849
- Artis Q, Siemens Medical Systems, K123529



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

December 12, 2013

Volcano Corporation  
% Ms. Elaine Alan  
Senior Regulatory Affairs Specialist  
1 Fortune Drive  
BILLERICA MA 01821

Re: K132558  
Trade/Device Name: Sync-Rx™ System  
Regulation Number: 21 CFR 892.1650  
Regulation Name: Image-intensified fluoroscopic x-ray system  
Regulatory Class: II  
Product Code: OWB  
Dated: September 13, 2013  
Received: September 16, 2013

Dear Ms Alan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

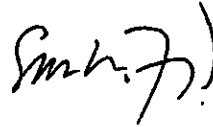
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Ms. Elaine Alan

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris  
Director, Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K132558

Device Name: Sync-Rx System

Indications for Use:

The Sync-Rx System is an image acquisition and processing system. It is indicated for use as follows:

- a) To provide quantitative information regarding the calculated dimensions of arterial segments.
- b) To enhance visualization of the stent deployment region.
- c) To be used in-procedure in the catheterization lab and off-line for post-procedural analysis.
- d) To obtain a co-registration of an angiographic x-ray image and IVUS images.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of Center for Devices and Radiological Health (CDRH)



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(Division Sign-Off)

Division of Radiological Health  
Office of In Vitro Diagnostics and Radiological Health  
510(k) K132558

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